

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
7 March 2002 (07.03.2002)

PCT

(10) International Publication Number
WO 02/17792 A1

(51) International Patent Classification: A61B 8/08

(21) International Application Number: PCT/HR01/00022

(22) International Filing Date: 7 May 2001 (07.05.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
P20000571A 1 September 2000 (01.09.2000) HR

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(81) Designated States (national): AE, AG, AL, AU, BA, BB, BG, BR, BZ, CA, CN, CO, CR, CU, CZ, DM, DZ, EE, GD, GE, HR, HU, ID, IL, IN, IS, JP, KR, LC, LK, LR, LT, LV, MA, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TT, UA, US, UZ, VN, YU, ZA.

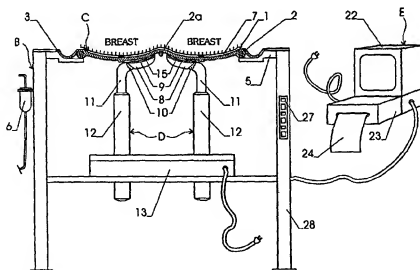
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICE FOR AUTOMATIC ULTRASOUND EXAMINATION OF THE BREASTS



(57) Abstract: The device for ultrasound examination of the breasts, by this invention, enables quick and simple examination of both breasts simultaneously, as part of a general physical examination. The device consists of the examination table (8) with frame (2) with silicone base (1), below which there are two probes (9) connected by support (11) to the probe head automatic lifting, lowering and rotating mechanism (13). The device is connected to instruments (E) that enable simultaneous monitoring of both breasts tissue on the monitor and printing it by a printer (23) into specially designed form that contains the patient's data, or on a computer diskette.

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DEVICE FOR AUTOMATIC ULTRASOUND EXAMINATION OF THE BREASTS

INVENTION DESCRIPTION

1. FIELD OF APPLICATION

The invention relates to device for automatic ultrasound examinations of breasts, that enables fast, mechanically performed, ultrasound test of the breasts as a part of the general physical examination. According to the International Patent Classification, it is classified as A 61 B 8/00.

2. TECHNICAL PROBLEM AND IMPLEMENTATION

One of the imperatives in women breast cancer diagnostics is an early detection by device that would enable obtaining relevant data sufficient for follow up and direct comparison of symmetricalness of the breast tissue structure in a simple, fast and low-cost-manner.

3. STATE OF ART

The present breast ultrasound examinations are performed manually and the very procedure is time consuming, requiring highly professional and specialised personnel who is to perform the examination, whereas its interpretation is a subjective description. The present examining methods do

not satisfy basic requirements of a fast and objective comparative examination.

4. DISCLOSURE OF THE INVENTION

The primary aim of the invention is the device for automatic ultrasound examination of the breasts.

The eventual aim is enabling a fast and simple, still by results a quality examination that would be more objective and comprehensive than the palpatory examination, with the possibility of following up processes in the breast tissue.

The breast ultrasound examination device, under the invention, includes examination table equipped with a frame with silicone base supplied with concavities for the breasts. The concavities are filled with water that flows into the water drainage canal and on into the sewage during the examination. At the silicone base undersides, there are two ultrasound probes moving over the convex silicone calottes during the examination. The probes are connected with the electric powered device that enables the probes to lift and rotate around the vertical axis. A holder with gel receptacle is fit in each probe. Gel lubricates the space between the probe and the silicon base. The probe is connected to the electronic device for recording the breasts, including a monitor and a printer for registering the breast structure status and printing it into a designed form, including also the patient's personal particulars.

Electronic controls control pressure and angle of the probes against the breasts through the silicon bases. When a satisfactory image is obtained on the monitor, the examiner starts recording the images. The probes rotate around the nipples and record at the same time, after which process the patient may leave the table and the clinic. The examination is performed very quickly.

It is to be underlined here that the invention enables examination of the breasts while the patient is in pronation, pressing the breasts against the silicon base, and that the examination is performed mechanically and not by manipulating the probes manually.

The related software enables data storing on CD ROM for the files and on floppy discs for the patient. This way, a patient may be followed-up whole her life on one CD ROM.

Making of programmes that enable automatic comparison of a patient's findings opens new possibilities in automatic reading and identification of changes in the breast tissue structure as related to previous findings.

5. BRIEF DESCRIPTION OF ILLUSTRATIONS

The drawings that are attached hereto and make a constitutive part of the invention description present the above described invention embodiment and help explaining its basic principles.

Figure 1. Examination table upper view.

Figure 2. Vertical cross-section A-A in the Fig. 1 through the silicon base with metal frame and water drainage canal.

Figure 3. Side view of the probe.

Figure 4. Position of particular recorded images as printed.

Figure 5. Gel receptacle holder.

Figure 6. Gel receptacle projected.

6. DETAILED DESCRIPTION OF THE INVENTION EMBODIMENT

This is a detailed description of the invention embodiment, as also illustrated by the attached drawings.

A) Description of the Invention Structure

The device consist of five basic assemblies:

- B - examination table,
- C - silicon base frame,
- D - probes with lifting, lowering, inclination and rotation mechanism,
- E - data recording and printing device,
- F - gel receptacle holder.

The examination table B, Figs. 1 and 2, consists of the upper surface 4, legs 28 and supports 5. In the surface 4, there is frame opening 2 with silicon base 1. At the side of the table, there are fitted water sprinkler 6 and the device controls unit 27.

The silicone base frame C, Fig. 1, is equipped with frame 2, silicone base 1, and water drainage canal 3. The frame outer edges are embedded in silicone unlike the inner edge 2a which is not and which acts as the silicone base support. The frame outer edges 2 lean on the support 5 on the table upper surface. At the silicone base 1 is supplied at its lateral edges with groove 3 for collecting water for taking it to sewage. The frame with the silicone base can be fitted to the lateral side of the examination table.

The silicone base 1 is to be smooth at both sides. In the calottes that establish contact between the breasts and the probes, the silicon base is thinner, whereas in the frame it can be thicker.

Probes with the lifting, lowering, inclination and rotation mechanism D, Fig. 2, consist of probe head 8 with piezoelectric plate 9 and joint 10 which enables the probe head to conform to the silicone base 1 calotte shape, depending on the breast volume. The probes are connected by the probe holder 11 and carrier 12 with the probe lifting, inclination and rotation mechanism, fitted in the housing 13, connected with mains to the power source. The probes rotate about the vertical axis 14 by 360° in both directions (Fig. 3).

The data recording and printing devices E, Fig. 2, is a standard set comprising a computer with a monitor 22 and printer 23. The (ultrasound scanner) monitor shows both breasts images at the same time, and the printer prints the form 24 containing the patient's personal particulars and images of both breasts tissue structures recorded radiantly. An inverse printout can be obtained, too, if required.

The gel receptacle with bearer F, Fig. 5, consists of the carrier 16, with opening 17 to receive the probe head 8 and opening 18 to receive the gel receptacle 19. The gel receptacle, Fig. 6, has gel outlets 20 and gel pressing piston 21.

B) Invention operation

To have her breasts examined, the patient lies prone onto the table upper surface 4, Fig. 2, and places her unclothed breasts onto the silicone base 1. To avoid presence of air, the space 15 between the breasts and the base 1 is previously to be wetted with the sprinkler 6, whereas exceeding water drains into groove 3 and further on into sewage, enabling, thus, a constant water flow.

A layer of gel 15 is placed between the silicon base 1 and the piezoelectric plate 9 on the probe head 8. Previously, the probe head 8 is pulled through the opening 17 of the gel receptacle holder 16, in which there is space 18 for fitting the gel receptacle 19. Gel is pressed out of the receptacle 19 through openings 20 with the piston 21. The probe holders 11 are automatically lifted to approach the silicon base 1 and take the initial recording position.

After this, there begins simultaneous recording of both breasts in one of two following ways:

1. One probe is phase shifted as compared to the other. This is achieved by taking pictures with each probe alternatively, images 25 and 26 being printed on the form 24 *parallelly*.

Example: 1st picture = 12^h L 2nd picture = 12^h R
 3rd picture = 1^h L 4th picture = 11^h R
 5th picture = 2^h L 6th picture = 10^h R etc.

2. Sequence of takes, when images from each probe are printed by separate printers for each breast.

Example: 1st picture = 12^h L 2nd picture = 1^h L & 12^h R
 3rd picture = 2^h L & 11^h R 4th picture = 3^h L & 10^h R
 5th picture = 4^h L & 9^h R etc.

- The probe position against the breast is denoted by position of hours on a clock face with the nipple in the centre, and the breasts by their sides L(left) and R(right).
- The shift between two takes prevents the probes to collide during the rotation.
- The two probes rotate in opposite directions (i.e., if the R probe rotates clockwise, the L probe rotates anticlockwise) so that the images show both breasts symmetrically at any given moment, which is important for reading the finds.
- The form printout shows continuous sequences of pictures of each breast, L and R being on the corresponding sides of the paper (Figs. 2 and 4).
- The recording can be saved at a CD ROM and, thus, permanently stored in the patient's medical file and, as a diskette, kept by the patient herself.

Thus, the described breasts examination procedure by this device is performed by the examinee laying down prone onto the examination table with her breast naked and laid on previously wetted silicone base. Then, both probes are lifted, by automatic controls, from underside to the silicone bases, between which there is previously applied gel from gel receptacle.

During examination, both breasts are positioned into the same position. The probe heads, then, rotate around the vertical axis that passes through the probe head console and record both breasts structure. The obtained recording is watched on connected monitor and printed by the printed into the prepared form with the patient's basic data. Subsequent comparison of the recorded breasts tissue structure with the basic appearance indicated possible changes in the breasts.

The above described procedure enables a fast ultrasound examination of the breasts within a general physical examination.

7. INVENTION APPLICATION

The breast examination performed by this device and procedure provides image record which enables noticing any suspicious changes based on knowledge of appearance of radiantly recorded breast tissue structures and the importance of the breast symmetricalness.

Presently, the entire breast changes diagnostics is based on a number of examinations, including the ultrasound, lasting about 20 minutes. Such examinations are too much time consuming and require too many expert examiners, this preventing a larger number of women to undergo timely examinations. However, the present breast cancer incidence makes examination of every single woman an imperative.

Examination by this device is intended for the primary health care and systematic physical examinations, because, by the way it is performed, it is as easy as measuring one's weight, height or blood pressure.

PATENT CLAIMS

1. The breasts ultrasound examination device, *wherein* the device consists of examination table (B), frame with silicone base (C), probe supplied with lifting, lowering, inclination and rotation mechanism (D), data recording and printing unit (E) and gel receptacle holder (F), the device, thus, enabling fast and simultaneous examination of both breasts and images recording of the breasts symmetrical structure, which enables studying of suspicious changes based on knowledge of the basic appearance of radiantly recorded breast tissue structures.
2. The device as claimed in the Claim 1, *wherein* on its upper table surface (B) there is an opening for receiving the frame with silicone base (C) and the frame support (5) equipped with water sprinkler (6) for watering the silicone base and with water drainage, and *wherein* below the upper surface there are located probes with probe lifting, lowering and rotating mechanisms (d).
3. The device as claimed in the Claim 1, *wherein* the frame with silicone base (C) consists of a hard frame (2) whose outer edges are embedded in silicone whereas the inner one (20) is free and carries the silicone base (1), which base is smooth and soft at both sides and has two breast concavities, and is also provided with a water collecting and draining canal (3).
4. The device as claimed in the Claim 1, *wherein* it is supplied with two probes for simultaneous examination of both breasts (E), each probe having head (8) with piezoelectric plate (9) that makes contact with the silicone base (1) underside, and *wherein* it is also supplied with a joint (10) that enables inclination of the probe head to adjust it to the silicon base calotte underside, depending on the breast volume, and *wherein* the heads rotate by 360° in both directions around an axis (14) passing

through the probe holder (11) which is connected through the support (12) with the probe automatic lifting and rotating mechanism (13).

5. The device as claimed in the Claims 1 - 4, *wherein* the frames with silicone bases (C) and both probes with the probe lifting, lowering, inclination and rotation mechanism (D) can be fitted at the lateral side of the examination table.
6. The device as claimed in the Claims 1 - 4, *wherein* onto the probe head (8) there is fitted gel receptacle (F) holder which is provided with openings for the probe head (17) and gel receptacle (19) so that gel is pressed out in the direction of the probe head rotation.
7. The device as claimed in the Claims 1 - 4, *wherein* it is supplied with gel receptacle (19) with opening for pressing gel out (20) and piston (21) for pushing gel from the receptacle into the space between the silicon base and the probe head piezoelectric plate.
8. The device as claimed in the Claims 1 - 4, connected to a data recording and printing unit (F), *wherein* this unit is supplied with a monitor (22) that show both breast images simultaneously and with a printer (23) that prints the recorded images on a form (24) together with the patient's personal particulars, as well as comparative imaged of same parts of both breasts tissue structures.
9. The device and procedure as claimed in the Claims 1 - 8, *wherein* it enables examination of the breasts of the patient in pronation and leaning her breasts against the silicone base, the vary examination being performed mechanically and not by manual probe manipulation.

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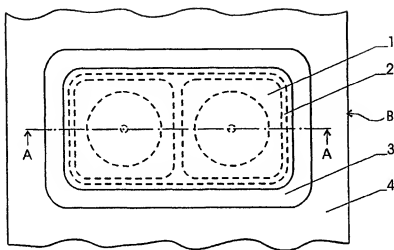


Fig. 1.

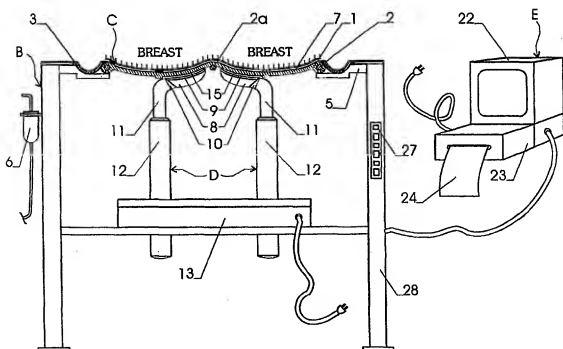
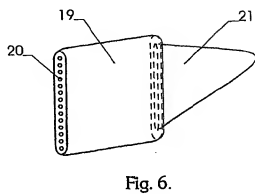
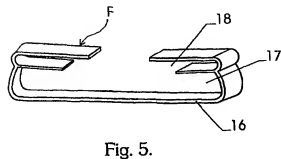
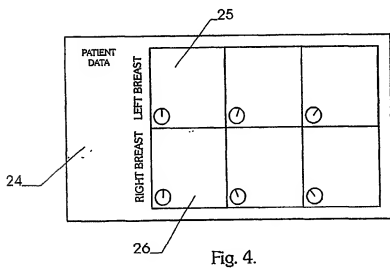
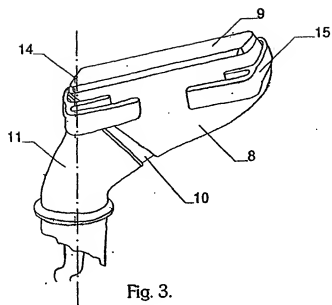


Fig. 2.

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INTERNATIONAL SEARCH REPORT

 International Application No.
 PCT/HR 01/00022

 A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	EP 0 089 682 A (SIEMENS AG) 28 September 1983 (1983-09-28) page 17, line 23 -page 20, line 20; figures 8,9 -/-	1-3,8,9

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 August 2001

Date of mailing of the international search report

28/08/2001

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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